

Notice of Allowability

Application No.

09/987,763

Examiner

Sumesh Kaushal Ph.D.

Applicant(s)

CRAFTON ET AL.

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/14/06.
2. ☒ The allowed claim(s) is/are 1,2,5-21,25,26,28-32,34,35,37 and 38.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Duane Stewart on 06/02/06.

The application has been amended as follows:

IN THE CLAIMS

1. (Currently Amended) An isolated polynucleotide ~~with the function of a promoter~~, comprising a first nucleic acid sequence operably associated with a second nucleic acid sequence, said first nucleic acid sequence consisting of a the nucleotide sequence that is:

(a) at least 95% identical to a the reference nucleotide sequence set forth in SEQ ID NO:7; or

(b) identical to a the reference nucleotide sequence set forth in SEQ ID NO:7; wherein said first nucleic acid sequence has the function of a promoter that regulates transcription of said second nucleic acid sequence in response to pyruvate.

2. (Original) The polynucleotide of claim 1, wherein said polynucleotide regulates transcription of β -galactosidase in a bacterial host cell.

3. (Canceled).

4. (Canceled)

5. (Currently Amended) The polynucleotide of claim 1, wherein said second nucleic acid encodes a polypeptide.

6. (Original) The polynucleotide of claim 5, wherein said polypeptide is selected from the group consisting of: (a) a polypeptide, which is a component of an amino acid biosynthesis pathway; (b) a polypeptide, which is a component of a purine nucleotide biosynthesis pathway; and (c) a heterologous polypeptide.

7. (Original) The polynucleotide of claim 6, wherein said polypeptide is a component of an amino acid biosynthesis pathway.

8. (Original) The polynucleotide of claim 7 wherein said amino acid biosynthesis pathway is a lysine biosynthesis pathway.

9. (Original) The polynucleotide of claim 7, wherein said polypeptide is selected from the group consisting of: (a) aspartokinase, (b) diaminopimelate dehydrogenase, (c) diaminopimelate decarboxylase, (d) dihydrodipicolinate synthetase, (e) dihydrodipicolinate reductase, (f) aspartate beta-semialdehyde dehydrogenase, and (g) pyruvate carboxylase.

10. (Original) A method of producing a vector which comprises inserting the polynucleotide of claim 1 into a vector.

11. (Original) A vector comprising the polynucleotide of claim 1.

12. (Currently Amended) A vector comprising the polynucleotide of claim 5.

13. (Original) A vector comprising the polynucleotide of claim 6.

14. (Currently Amended) ~~[[A]]~~ An isolated host cell comprising the vector of claim 11.

15. (Original) The host cell of claim 14, wherein said host cell is a *Corynebacterium* species.

16. (Currently Amended) ~~[[A]]~~ An isolated host cell comprising the vector of claim 12.

17. (Currently Amended) ~~[[A]]~~ An isolated host cell comprising the vector of claim 13.

18. (Currently Amended) A method of producing ~~[[a]]~~ an isolated transformed *Corynebacterium* species host cell comprising: (a) introducing into *Corynebacterium* species cells the vector of claim 17, and (b) selecting said host cell.

19. (Original) A method of production of a biosynthetic product, comprising culturing the host cell of claim 18 in or on a culture medium, and recovering said product.

20. (Currently Amended) An isolated polynucleotide comprising a first nucleic acid sequence operably associated with a second nucleic acid sequence, said first nucleic acid sequence consisting of ~~[[a]]~~ the nucleotide sequence at least 90% identical to the sequence set forth in SEQ ID NO: 7, and wherein the -10 region of said nucleotide sequence consists ~~essentially~~ of the sequence TACAAT and wherein the -35 region of said nucleotide sequence consists ~~essentially~~ of the sequence TTGCCA₁, wherein said first nucleic acid sequence has the function of a promoter that regulates transcription of said second nucleic acid sequence in response to pyruvate.

21. (Original) The polynucleotide of claim 20, wherein said polynucleotide regulates transcription of β -galactosidase in a bacterial host cell.

22-24. (Canceled).

25. (Previously Presented) An isolated polynucleotide comprising a first nucleic acid sequence operably associated with a second nucleic acid sequence, wherein the sequence of said first nucleic acid ~~comprises~~ consists of at least 50 contiguous nucleotides of SEQ ID NO:7.

26. (Currently Amended) The polynucleotide of claim 25, wherein ~~the sequence of said first nucleic acid~~ sequence ~~comprises~~ consists of at least 150 contiguous nucleotides of SEQ ID NO:7.

27. (Canceled)

28. (Currently Amended) The polynucleotide of claim ~~[[27]]~~ 25, wherein said second nucleic acid encodes a polypeptide.

29. (Original) The polynucleotide of claim 28, wherein said polypeptide is selected from the group consisting of: (a) a polypeptide which is a component of an amino acid biosynthesis pathway; (b) a polypeptide which is a component of a purine nucleotide biosynthesis pathway; and (c) a heterologous polypeptide.

30. (Original) The polynucleotide of claim 29, wherein said polypeptide is a component of an amino acid biosynthesis pathway.

31. (Previously Presented) A method of producing a vector which comprises inserting the polynucleotide of claim 25 into a vector.

32. (Previously Presented) A vector comprising the polynucleotide of claim 25.
33. (Canceled)
34. (Currently Amended) [[A]] An isolated host cell comprising the vector of claim 32.
35. (Previously Presented) The host cell of claim 34, wherein said host cell is a *Corynebacterium* species.
36. (Canceled)
37. (Original) A method of producing a transformed *Corynebacterium* species host cell comprising: (a) introducing into *Corynebacterium* species cells the vector of claim [[33]] 32, and (b) selecting said host cell.
38. (Original) A method of production of a biosynthetic product, comprising culturing the host cell of claim [[36]] 34 in or on a culture medium, and recovering said product.
- 39-73. (Canceled).

REASONS FOR ALLOWANCE


The following is an examiner's statement of reasons for allowance: Claims 1-2, 5-21, 25-26, 28-32, 34-35 and 37-38 are free of prior art of record. The prior art does not teach or suggest the nucleotide sequence of the SEQ ID NO:7, which is the IdhA gene promoter that regulates the transcription of a nucleic acid sequence operably linked thereto in response to pyruvate. In addition, the applicant provides evidence that the SEQ ID NO:7 has homology to known idh-promoter sequences (*see applicant's declaration filed on 03/08/06*)

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 571-272-0769. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on 571-272-0731.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to **571-272-0547**. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**


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PRIMARY EXAMINER
ART UNIT 1633